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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,099	Applicant(s) TSANG ET AL.	
	Examiner Daniel M Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/10/04; 6/28/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the First Office Action on the Merits of the application filed 10 February 2004 as a divisional of US application 09/895,585 filed 29 June 2001, which claims benefit of US provisional applications 60/291,787 filed 17 May 2001, 60/246,306 filed 6 November 2000 and 60/215,634 filed 30 June 2000. Claims 1-19 were originally filed and claims 7-10 and 15-19 were canceled in an amendment filed concurrently with the application. Claims 1-6 and 11-14 are pending.

Election/Restrictions

Applicant's election of Group II in the reply filed on 18 November 2004 is acknowledged. It is noted that Group II, as set forth in the restriction requirement, includes claims 13 and 14, not claims 11-14 as stated by applicant. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, Applicant's right to reconsideration of the restriction requirement upon allowance of the product claims is acknowledged.

Claims 1-6, 11 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 November.

Claims 13 and 14 are presently under consideration.

Specification

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The abstract of the disclosure is objected to because it includes the title of the application as a heading. It is generally preferable that the abstract be set forth as a single paragraph and the inclusion of a title, which will be printed on the cover of the patent independent of the abstract, is unnecessary. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: The specification is objected to because it contains typographical errors. For example, the word “may” is misspelled in the 32nd line on page 13. Applicant is urged to review the specification and correct any additional typographical errors therein.

Appropriate correction is required.

It is also noted that the priority claim in the first line of the specification does not reflect the current status of application 09/895,585 as US Patent No. 6,759,039. Applicant is requested to amend the priority claim to include reference to the ‘039 patent.

Claim Objections

Claim 13 is objected to because of the following informalities: The claim depends from a non-elected claim. Amending claim 13 to recite the limitations of claim 1 would be remedial. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13 and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 10/326,190. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that is recited in claim 7 of the '190 application. The instant claims are directed to a culture of propagating pancreatic cells having the ability to be passed from one culture vessel to a second vessel at an initial concentration of about 180 cells per square centimeter while retaining 90% PDX-1 positive and an insulin:actin mRNA ratio of between 1:100 and 1000:1. Claim 7 of the '190 application is directed to a composition comprising encapsulated cells having the properties of the cells of the instant claims 13 and 14 and further requiring that the unexpanded, as well as expanded, cells are 90% PDX-1 positive and have an insulin:actin mRNA ratio of between 1:100 and 1000:1. The culture of propagating pancreatic cells of the instant claims is anticipated by claim 7 of the '190 application and, therefore, would be obvious to one of ordinary skill based on the '190 application claim alone.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Beattie *et al.* (1999) *Diabetes* 48:1013-1019 or Nielsen *et al.* (1989) *Mol. Endocrinol.* 13:165-173.

Claim 14 is directed to a culture of propagating pancreatic cells “having the ability to be passed from one culture vessel to a second vessel at an initial concentration of about 180 cells per square centimeter while retaining 90% PDX-1 positive and an insulin:actin mRNA ratio of between 1:100 and 1000:1”. The broadest reasonable interpretation of the pancreatic cell of the claims is that it is not incapable of exhibiting the phenotype recited. That is, any cell that, given the proper treatment or manipulation, could reasonably be expected to exhibit the recited phenotype “has the ability” to exhibit that phenotype. In the paragraph bridging pages 13-14, the specification teaches, “[t]he intermediate cell population of the present invention may [sic] arise all or in part by differentiation of facultative stem cells, dedifferentiation of mature endocrine cells, or by transdifferentiation of other pancreatic cell populations.” In addition, the paragraph bridging pages 15-16 of the specification teaches that islet-cell enriched cell populations are capable of giving rise to the intermediate cell population described in the application. Thus, the specification appears to teach that a variety of pancreatic cells, including islet cells, possess the inherent ability to be passed from one culture vessel to a second vessel at an initial concentration

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of about 180 cells per square centimeter while retaining 90% PDX-1 positive and an insulin:actin mRNA ratio of between 1:100 and 1000:1.

Both Beattie *et al.* and Nielsen *et al.* teach a culture of propagating pancreatic cells enriched in islet cells (see especially Beattie *et al.*, the fourth and fifth full paragraphs in the right column on page 1013 and Figure 4, the first full paragraph on page 1016 and Figure 4 and the caption thereto; see also Nielsen *et al.*, the abstract, the second full paragraph in the right column on page 165 and the paragraph bridging pages 165-167). Based on the teachings of the specification and the absence of evidence to the contrary, these cells “have the ability” to be passed from one culture vessel to a second vessel at an initial concentration of about 180 cells per square centimeter while retaining 90% PDX-1 positive and an insulin:actin mRNA ratio of between 1:100 and 1000:1. Therefore, the culture of claim 14 is anticipated by the art.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beattie *et al.* (*supra*) or Nielsen *et al.* (*supra*).

The use of 35 U.S.C. §102/103 rejections for product-by-process claims has been approved by the courts. “[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the

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claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

The instant claim 13 is directed to a culture of propagating pancreatic cells produced by a method giving rise to a population of propagating pancreatic cells having the ability to be passed from one culture vessel to a second vessel at an initial concentration of about 180 cells per square centimeter while retaining 90% PDX-1 positive and an insulin:actin mRNA ratio of between 1:100 and 1000:1. Although the cultures of propagating pancreatic cells taught by Beattie *et al.* and Nielsen *et al.* are not obtained using the same process as recited in the instant claims, the product appears to be the same as the product of the instant claims. As discussed above, the recited phenotype requires only that the culture “have the ability” to exhibit the recited phenotype. Absent evidence to the contrary, the cultures of Beattie *et al.* and Nielsen *et al.* would have this ability (*Id.*). Therefore, the claim is anticipated by or, in the alternative, obvious over Beattie *et al.* and Nielsen *et al.*

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636